GE Healthcare

December 21, 2007

JAN 25 2008

2. 510(k) Summary

Date: 12/17/2007

Submitter: GE Medical Systems *Information Technologies* 9900 Innovation Drive
Wauwatosa, WI 53226 USA

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GE Medical Systems *Information Technologies*
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Secondary Contact: Matthias Buerger
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Diagnostic Cardiology
GE Medical Systems *Information Technologies*
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Device: Trade Name: MAC 5500 ECG Analysis System

Common/Usual Name: Electrocardiograph

Classification Names[1]:

21 CFR 870.2340	Electrocardiograph	DPS
21 CFR 870.1425	Programmable Diagnostic Computer	DQK
21 CFR 870.2920	Transmitters and Receivers, Electrocardiograph, Telephone	DHX

Predicate Device: K042177 MAC 5500 ECG Analysis System

Device Description: The MAC 5500 ECG Analysis System is designed to acquire, analyze, display, and record ECG signals from surface ECG electrodes. The device consists of two basic components: the processing unit and the patient acquisition module. Models provide rechargeable battery operation and/or optional trolley for transporting the equipment.

[1] The Classification Names/Numbers and Code assigned during the clearance of the MAC 5500 ECG Analysis System for K042777 was MHX – Detector Arrhythmia Detector and Alarm (including ST-segment measurement and alarm) (870.1025). GE Medical Systems Information Technologies formally requested on 12/14/07 that the MAC 5500 ECG be reclassified as DPS – Electrocardiograph (870.2340) as this code more accurately reflects the intended use of this device as this device is not intended to detect an arrhythmia and alarm or produce an audible signal when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation occurs, which is the *Identification* statement contained in Code MHX (Section 870.1025). The intended use more closely matches the *Identification* statement for Section 870.2340 Electrocardiograph, which states that an Electrocardiograph is a device used to process the electrical signal transmitted through two or more electrocardiograph electrodes and to produce a visual display of the electrical signal produced by the heart. This submission is reflective of this requested code change to DPS for the MAC 5500.

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Device Description: (continued)

The MAC 5500 can deliver 3, 6, 12, or 15 lead ECG's, interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5500 system acquires ECG data using the CAM14 patient data acquisition module. By placing the data acquisition device closer to the patient, signal fidelity is improved and noise is reduced. MAC 5500 delivers 12 or 15 lead ECG's on full-size reports. The MAC 5500 incorporates a alphanumeric keyboard for patient demographics and other data entry, a full size VGA graphics and waveform display, an integrated thermal writer and removable data storage.

Additionally, the MAC 5500 utilizes battery power for customer convenience and can transmit and receive ECGs to and from a central ECG cardiovascular information system via optional communication links. The system is intended as a mobile device but the main unit can be separated from the trolley and used as a desktop unit.

Indications for Use

The MAC 5500 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5500 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Technology

The MAC 5500 ECG Analysis System employs the same functional technology as the predicate devices.

Conclusion:

The results of these measurements demonstrated that the MAC 5500 ECG Analysis System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

GE Medical Systems Information Technologies
c/o Ms. Margaret Mucha
Regulatory Affairs Leader
9900 Innovation Drive
Wauwatosa, WI 53226

Re: K073625
Trade/Device Name: MAC 5500 Resting ECG Analysis System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II (two)
Product Code: DPS, DQK, DHX
Dated: December 21, 2007
Received: December 26, 2007

Dear Ms. Mucha:

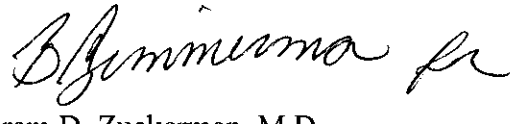
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GE Healthcare

December 21, 2007

3. Intended Use

510(k) Number (if known):

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Device Name: MAC 5500 ECG Analysis System

Intended Use:

The MAC 5500 ECG Analysis System is intended to acquire, analyze, display, and record electrocardiographic information adult and pediatric populations. Basic systems deliver 3, 6, 12, or 15 lead ECG's, interpretive analysis, vector loops, and can be upgraded to provide software analysis options such as high resolution signal averaging of QRS and P wave portions of the electrocardiogram. Transmission and reception of ECG data to and from a central ECG cardiovascular information system is optional.

The MAC 5500 is intended to be used under the direct supervision of a licensed healthcare practitioner, by trained operators in a hospital or medical professional's facility.

Prescription Use_X_ OR Over-The-Counter Use____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073605